

EXHIBIT F

Jimmy W. Mays, Ph.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC
REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

Master File No.
2:12-MD-02327

MDL NO. 2327

THIS DOCUMENT RELATES TO THE
FOLLOWING CASES IN WAVE 1 OF MDL
200:

JOSEPH R. GOODWIN
US DISTRICT JUDGE

Bonnie Blake, et al., v. Ethicon,
Inc., et al.,
Civil Action No. 2:12-cv-00995
Robin Bridges v. Ethicon, Inc.,
et al.,
Civil Action No. 2:12-cv-00651
Carey Beth Cole, et al., v.
Ethicon, Inc., et al.,
Civil Action No. 2:12-cv-00483
(Continued on next page)

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MARCH 2, 2016

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Deposition of JIMMY W. MAYS, PhD, held at
Marco Island Marriott Beach Resort, South Collier
Boulevard, Marco Island, Florida, commencing
at 8:36 a.m., on the above date, before Joan L.
Pitt, Registered Merit Reporter, Certified
Realtime Reporter, and Florida Professional
Reporter.

- - -

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1 materials.

2 Q. And you've never personally inspected a mesh
3 explant of Prolene, have you?

4 A. No.

5 Q. Have you ever done any testing of a mesh
6 explant of Prolene?

7 A. Not of Prolene.

8 Q. And, Doctor, are you -- do you know what
9 medical products you're here and designated to testify
10 about and give opinions about?

11 A. Yes, I do. They're listed at the beginning of
12 my report.

13 Q. Where do you see that?

14 A. If you go over on page 4, under background, the
15 various Prolene mesh products are listed there.

16 Q. Sir, do you know if all those products -- and
17 just for the record, we're looking at Prolene Mesh,
18 Gynemesh PS, Prolift, Prolift +M, Prosima, TVT-Secur --
19 I'm sorry -- Gynecare TVT System, TVT Retropubic, TVT-O,
20 TVT-Abbrevio, TVT-Secur, and TVT-Exact; is that correct?

21 A. I'm sorry. Could you --

22 Q. Is that the list of the medical --

23 A. That is the list, yes.

24 Q. And, Doctor, do you know if all those products

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1 additives are present at a very low level.

2 Q. But to be exact, polypropylene is chemically
3 different than Prolene; correct?

4 A. Well, polypropylene as it's encountered in the
5 marketplace essentially always has these additives in
6 it. Processing aids and antioxidants are always put
7 into polypropylene.

8 Q. Right, but, Doctor, my question is more
9 specific. Is it your testimony that polypropylene and
10 Prolene are chemically different or chemically the same?

11 A. Prolene is a particular formulation of
12 polypropylene.

13 Q. So they're chemically different; correct?

14 A. There are additives added.

15 Q. But they are chemically different?
16 Polypropylene is chemically different than Prolene;
17 correct?

18 A. Well, Marlex versus Prolene, the base polymer
19 in both is isotactic polypropylene. There may be
20 different additives in there. There may be different
21 molecular weights of polypropylene use. There may be
22 different molecular weight distributions of the
23 polypropylene that's used. So Prolene is a particular
24 formulation of polypropylene.

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1 **Q.** I understand that, Doctor, but Prolene has a
2 different chemical composition compared to pure
3 polypropylene; correct?

4 **A.** Compared to pure polypropylene, that's correct.

5 **Q.** Thank you. And Prolene and polypropylene are
6 not identical from a chemical composition standpoint,
7 are they?

8 **A.** Polypropylene is the major component in
9 Prolene.

10 **Q.** Right, but they are not chemically identical,
11 are they, sir?

12 **A.** The additives make them different. Prolene has
13 the additives. Pure polypropylene would not.

14 **Q.** And you'd never teach your polymer students at
15 UT that Prolene and polypropylene have the same chemical
16 composition, would you?

17 **A.** No, I would teach them that Prolene is an
18 isotactic polypropylene with a certain additive package
19 in it.

20 **Q.** Let's talk about polypropylene specifically, if
21 you will. You've studied polypropylene before, I take
22 it, as a scientist?

23 **A.** Yes.

24 **Q.** When did you begin doing that?

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1 Have you personally performed any testing to
2 determine if Prolene degrades?

3 A. We have performed testing to determine whether
4 or not polypropylene --

5 Q. And I'm not -- I don't mean to cut you off, but
6 I am under a time limit. I'm talking about Prolene.

7 Have you personally done any testing to
8 determine if Prolene degrades?

9 A. We have tested polypropylene pelvic mesh. That
10 was a Boston Scientific product. But these materials
11 are 99.8 percent polypropylene.

12 Q. And move to strike as nonresponsive.

13 Doctor, I'm asking you a specific question. I
14 need a yes or no. Have you personally performed any
15 testing to determine if Prolene degrades?

16 A. We have tested polypropylene, but we have not
17 tested Prolene.

18 Q. Thank you. And, Doctor, you've not tested the
19 mechanical properties of Prolene, have you?

20 A. We have not.

21 Q. Doctor, have you done any tests on Prolene that
22 can be repeated and confirmed? I'm talking about
23 Prolene, not polypropylene.

24 A. Yeah. We have not in my laboratory tested

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1 Prolene.

2 Q. Doctor, have you ever done -- and when you say
3 you have not in your laboratory tested Prolene, would
4 that include a pristine piece of Prolene and also an
5 explanted piece of Prolene?

6 A. Yeah, again, as I said earlier, we may have
7 characterized some material that was sent to us by
8 someone at some point, probably in terms of a molecular
9 weight analysis or something like that, but I don't
10 recall testing Prolene.

11 Q. Doctor, have you ever personally seen a Prolene
12 explant that has degraded?

13 A. I've seen pictures, but I haven't actually with
14 my own two eyes seen the degraded Prolene explant.

15 Q. And, Doctor, with your own two eyes, have you
16 ever seen oxidated Prolene?

17 A. With my own two eyes, I'd have to say no.

18 Q. Doctor, with your own two eyes, have you ever
19 personally seen Prolene with embrittlement?

20 A. No.

21 Q. Have you ever with your own two eyes personally
22 seen Prolene that has a loss of mechanical properties?

23 A. What do you mean by "loss of mechanical
24 properties"?

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1 **Q.** A reduction in the physical properties.

2 **A.** Which ones?

3 **Q.** Any of them.

4 **A.** Have I actually seen that material with my own
5 eyes?

6 **Q.** Yes, sir.

7 **A.** No.

8 **Q.** Thank you. And, in fact, Doctor, you've never
9 tested the durability of Prolene, have you?

10 **A.** No.

11 **Q.** You've never tested the tensile strength of
12 Prolene, have you?

13 **A.** No.

14 **Q.** You've never tested the toughness of Prolene,
15 have you?

16 **A.** No.

17 **Q.** You've never tested any type of physical
18 property of Prolene, have you?

19 **A.** No.

20 **Q.** You've never done any type of benchtop testing
21 of Prolene, have you?

22 **A.** No.

23 **Q.** And you've never done any root cause analysis
24 to determine if Prolene is defective, have you?

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1 **A.** Yes, I think I have.

2 **Q.** What?

3 **A.** Basically, I reviewed extensive literature,
4 both Ethicon internal literature where they observed
5 degradation of explanted Prolene, and I also reviewed
6 extensive literature. I could go through paper by
7 paper, if you like, and they observed degradation of
8 Prolene implants.

9 **Q.** And we're going to get to that, but outside of
10 literature, Doctor, have you ever done any -- outside of
11 your literature review, have you ever done any type of
12 root cause analysis to determine if Prolene is
13 defective?

14 **A.** We have explored the mechanism by which
15 polypropylene mesh degrades inside the body.

16 **Q.** Okay. And I'm sorry if my question wasn't
17 clear. I was asking about Prolene.

18 So outside of literature, Doctor, have you ever
19 done any type of root cause analysis to determine if
20 Prolene is defective?

21 **A.** What do you mean by "root cause analysis"?

22 **Q.** Any type of analytical study to determine if
23 Prolene is defective.

24 **A.** You mean actually perform experiments on

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1 Prolene? No.

2 Q. Doctor, have you ever performed any type of
3 accelerated aging tests for Prolene?

4 A. No.

5 Q. Doctor, you've cleaned mesh before, have you
6 not?

7 A. Yes.

8 Q. Have you personally been involved in that
9 process?

10 A. Yes, I have.

11 Q. And was that with the 11 explants in Boston
12 Scientific?

13 A. Yes.

14 Q. Have you ever personally cleaned Prolene mesh?

15 A. No.

16 Q. Have you ever been involved in any type of
17 cleaning protocols for Prolene mesh?

18 A. With developing the cleaning protocol?

19 Q. For Prolene mesh. Not polypropylene. Prolene
20 mesh.

21 A. No, we haven't cleaned Prolene mesh.

22 Q. And -- but you haven't been involved in any
23 cleaning protocols for Prolene mesh; correct?

24 A. There's an ASTM protocol, and that's what we

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1 use when we clean polypropylene.

2 Q. Right, but I'm asking about your personal
3 experience, Doctor. You've never been involved in any
4 cleaning protocols for Prolene mesh; correct?

5 A. No. Correct.

6 Q. Doctor, look back at Exhibit 1 for me, please.
7 That's a notice of deposition?

8 A. Yes.

9 Q. I'll represent to you that you're designated in
10 28 different lawsuits. Does that look about right?

11 A. That looks about right.

12 Q. Do you know what -- and each lawsuit represents
13 the name of a plaintiff that received a Prolene implant;
14 correct?

15 A. Correct.

16 Q. Do you know what product these 28 women
17 received?

18 A. All I know is it was Prolene, a Prolene-based
19 mesh.

20 Q. You never reviewed medical records?

21 A. No.

22 Q. Never talked to any of the doctors?

23 A. No.

24 Q. Never inspected any of the explants from these

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1 Q. But my question is: Do you know the specific
2 reason why any of these 28 plaintiffs' mesh was removed?

3 A. No, I don't.

4 Q. You don't know when these 28 plaintiffs' meshes
5 were implanted, do you?

6 A. I do not have those records, no.

7 Q. And you don't know when they were explanted?

8 A. No.

9 Q. Do you know how many pieces of an explant was
10 removed?

11 A. No.

12 Q. And do you know if these 28 plaintiffs'
13 explants were stored in formalin?

14 A. No.

15 Q. You would agree that if explants exist for
16 these 28 plaintiffs, that would be an important piece of
17 evidence in this litigation; correct?

18 A. That would be, yes.

19 Q. And would you like to review those explants?

20 A. Sure.

21 Q. And have you asked the plaintiffs' lawyers for
22 the permission to review those explants?

23 A. I have not.

24 Q. Why not?

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1 **A.** Well, I might very well at some point in time.
2 The first step was to get familiar with the case and
3 file my report.

4 **Q.** Doctor, have you ever seen any type of
5 histology slides from any of these 28 plaintiffs?

6 **A.** Not to my knowledge.

7 **Q.** Would you review histology slides if they were
8 available?

9 **A.** I'd certainly look at them.

10 **Q.** Have you asked for them?

11 **A.** I have not.

12 **Q.** Doctor, have you ever performed -- strike that.
13 Fair to say that you've never performed any
14 type of analytical testing on the explants of these 28
15 plaintiffs; correct?

16 **A.** Correct.

17 **Q.** You've never done any type of SEM, FTIR, DSC,
18 EDS, GPC on these plaintiffs' explants; correct?

19 **A.** Correct.

20 **Q.** Doctor, have you -- strike that.

21 I think we talked about this earlier, but it's
22 undisputed that degradation affects the physical
23 properties of mesh; correct?

24 **A.** Yes.

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1 **A.** My experience with polypropylene, my
2 characterization of polypropylene-based meshes.

3 **Q.** Do you base --

4 **A.** The literature that Ethicon has in-house going
5 back to the early '80s where they again and again see
6 evidence of oxidative degradation of polypropylene
7 implants.

8 **Q.** Doctor, you've never personally run any type of
9 oxidation tests on Prolene; correct?

10 **A.** To my knowledge, not on Prolene.

11 **Q.** And you've never done a molecular weight test?

12 **A.** We've done a lot of molecular weight tests.

13 **Q.** On Prolene?

14 **A.** As I said earlier, we may have in the polymer
15 characterization lab at some time, but I don't recall
16 explicitly doing molecular weight determinations on
17 Prolene.

18 **Q.** Okay. And you would have done that by GPC;
19 correct?

20 **A.** Yes. It's not the only way to determine
21 molecular weight, but it's a very common way to do it.

22 **Q.** And, Doctor, those analytical testing
23 techniques were available to you at your lab at UT;
24 correct?

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1 Q. But you don't know for sure, do you, sir?

2 A. Not in the case of Clave.

3 Q. Okay. Thank you.

4 A. I haven't seen firm evidence. But then I've
5 also got the internal Ethicon documents.

6 Q. We're going to get to those in a minute, but
7 I'm talking about the peer-reviewed literature. Okay?

8 A. Okay.

9 Q. So we'll get to those in a minute, but let's
10 stick with the peer-reviewed literature.

11 A. Okay.

12 Q. Jongebloed, Mary, and Costello are the only
13 literature regarding Prolene that you base your opinions
14 on; is that correct?

15 A. Yes.

16 Q. Okay. And, Doctor, I forgot to ask you about
17 this earlier, but when we were talking about physical
18 and mechanical property testing, you'll agree that
19 mechanical properties and the evaluation of mechanical
20 properties is relevant when determining whether or not
21 mesh degrades?

22 A. I don't think it's necessarily relevant. One
23 can determine if a material is degrading by
24 spectroscopic means, chemical changes in the material,

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1 or one could look at molecular weight changes in the
2 material. If chains are being broken, degradation is
3 happening.

4 Those changes manifest themselves in changes in
5 mechanical properties, but they're not the direct
6 observation of the degradation process. You're
7 measuring the consequences of degradation with those
8 studies.

9 Q. Doctor, but, nevertheless, evaluating
10 mechanical properties and physical properties are an
11 important part in your analysis of whether or not a
12 material degrades; correct?

13 A. No. As I just said, degradation can be
14 established with spectroscopy, with microscopy, with gel
15 permeation chromatography, with light scattering, and
16 other molecular methods.

17 Q. Can degradation be established by reduction in
18 physical properties?

19 A. If one measures a material and sees a reduction
20 in mechanical properties, again, just speaking
21 generically about mechanical properties at this point,
22 if one sees a change, then one might suspect degradation
23 is taking place, yes.

24 Q. All right. And just so the record's clear,

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1 degradation can be established by reduction in physical
2 properties; correct?

3 **A.** No, molecular level degradation needs
4 spectroscopy or molecular weight measurements.
5 Mechanical properties -- changes in mechanical
6 properties are merely an outcome of the chemical
7 changes. They're not direct.

8 **Q.** Doctor, would you ever tell your students at UT
9 to disregard the results of physical properties when
10 making a determination of whether or not a polymer has
11 degraded?

12 **A.** Well, if they had that material at hand,
13 certainly they would factor it into the analysis, but
14 it's not the direct analysis of whether or not a
15 material has degraded.

16 **Q.** I understand that, sir, but you will agree that
17 it is one piece of the puzzle on whether or not a
18 polymer has degraded; correct?

19 **A.** It's a piece of the puzzle, but it's a
20 secondary piece of the puzzle. It's not a primary one.

21 **Q.** Doctor, do you have any evidence that any of
22 these 28 plaintiffs experienced any type of chronic pain
23 related to Prolene?

24 **A.** No direct evidence, but they had their mesh

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1 taken out, and I assume they had problems with it, or
2 they wouldn't be suing Ethicon.

3 Q. That's an assumption on your part; correct?

4 A. It is. It is.

5 Q. And, Doctor, can you identify by name a single
6 person who has had a failure of their mesh for the
7 reasons that you outline in your report?

8 A. I would say that oxidative degradation is at
9 the heart of the problems that all of these people had
10 with the mesh and it's the reason that there's multiple
11 mesh companies with thousands of lawsuits around.
12 People are having problems with polypropylene mesh.
13 It's fundamentally the wrong material to make a pelvic
14 mesh out of.

15 Q. Doctor, can you identify by name a single
16 person who has had a failure of their mesh for the
17 reasons outlined in your report?

18 A. Again, all these people --

19 Q. I'm just asking for a name.

20 A. All of these people, Bonnie Blake, Robin
21 Bridges, Carey Beth Cole, these people had problems with
22 their mesh.

23 Q. How did Bonnie Blake's mesh fail?

24 A. Oxidative degradation is at the core of what's

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1 of these removals, so every individual listed here.

2 Q. Okay. And, Doctor, how do you know that Bonnie
3 Blake's mesh was removed because of degradation without
4 reviewing the medical records?

5 A. It's made out of polypropylene. Polypropylene
6 is attacked inside the human body with strong oxidizing
7 agents.

8 Q. Does Bonnie Blake have any mesh that's made out
9 of Prolene?

10 A. I have to assume that her mesh was made out of
11 Prolene because she's suing Ethicon.

12 Q. Do you know if Bonnie Blake has mesh that's
13 made out of Prolene?

14 A. I think it's a logical conclusion to reach.

15 Q. My question is: Do you know, sir, whether or
16 not Bonnie Blake has mesh that's made out of Prolene?

17 A. I have not reviewed her medical records. Okay?

18 Q. But my question is: Do you know if Bonnie
19 Blake has mesh that's made out of Prolene? Yes or no?

20 A. Yes.

21 Q. And what do you base that on?

22 A. The fact that she's suing Ethicon.

23 Q. Doctor, you're not a clinician?

24 A. I'm not.

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1 **Q.** And you haven't -- have you ever reviewed a
2 medical record that says the surgeon is removing Prolene
3 mesh as a result of degradation?

4 **A.** I don't review medical records normally. I'm a
5 polymer scientist. I'm a polymer chemist. The
6 chemistry of polymers, the characterization of polymers,
7 is my thing. I'm not a medical doctor.

8 **Q.** I understand that, Doctor, but my question is:
9 Have you ever reviewed a medical record that says a
10 surgeon is removing Prolene mesh as a result of
11 degradation?

12 **A.** I have not.

13 **Q.** Doctor, have you done anything whatsoever to
14 explain how the alleged effects of degradation have
15 caused clinical harm to any of these 28 plaintiffs?

16 **A.** Well, my report describes what happens to the
17 properties of polypropylene when they undergo
18 degradation, and it's the mechanical mismatch between
19 the degraded implants and the soft tissue that surrounds
20 it that's the root cause of these problems.

21 **Q.** Do you know the symptoms that any of these 28
22 plaintiffs were complaining about?

23 **A.** Individual symptoms will vary, but pain is a
24 very common one.

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1 additives, such as processing aids and antioxidants,
2 yes.

3 Q. Doctor, I know that you've worked for --
4 against, rather -- Boston Scientific. Have you ever
5 done any type of analytical testing of pelvic mesh
6 explants other than in Boston Scientific?

7 A. No.

8 Q. And, Doctor, are you -- did you perform any
9 type of physical property testing of the pelvic explants
10 in the Boston Scientific litigation?

11 A. We measured the materials by spectroscopy, we
12 did GPC, we looked at the materials with
13 thermogravimetric analysis, SEM with EDS, but we did not
14 measure mechanical properties of those materials.

15 Q. Why not?

16 A. We were interested in determining what caused
17 the degradation of those materials once we noted the
18 degradation, and we used spectroscopy and GPC to do it.
19 As I mentioned earlier, those are the primary tools that
20 one would use to get direct evidence of degradation and
21 to identify what's causing the degradation.

22 Q. Doctor, you'll agree that the adherence to
23 protocols and controls is the hallmark of good science?

24 A. Yes.

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1 to have to spell, probably, a few of those.

2 THE WITNESS: We'll do that.

3 MR. HUTCHINSON: Yeah.

4 THE WITNESS: We'll do that.

5 BY MR. HUTCHINSON:

6 Q. But -- I'm sorry. You're not an expert in the
7 design of surgical mesh?

8 A. Actually designing the mesh, the geometry, the
9 shape, no, I'm not.

10 Q. And, Doctor, you testified in Boston Scientific
11 that polypropylene meshes should not be available to
12 doctors to treat SUI or POP. Do you recall that?

13 A. Yes.

14 Q. And do you stand by that?

15 A. Yes, I do.

16 Q. Doctor, you testified that polypropylene
17 vaginal mesh is a very bad idea. Do you stand by that?

18 A. I do.

19 Q. And you've never shared those views with any
20 physicians at UT; is that right?

21 A. Yes, I have.

22 Q. When did you do that?

23 A. I did that late summer/early fall of last year.

24 Q. And you did that after you were cross-examined

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1 about that; correct?

2 A. Yeah, I did.

3 Q. Doctor, have you ever told the doctors at UT
4 that Prolene mesh should not be used to treat SUI or
5 POP?

6 A. I cautioned them about polypropylene mesh
7 broadly.

8 Q. Okay. But my question is specifically about
9 Prolene. Have you ever told the doctors at UT that
10 Prolene mesh should not be used to treat SUI or POP?

11 A. When I told them that polypropylene mesh should
12 not be used, that it's a bad idea, that it's susceptible
13 to degradation inside the human body, they should know
14 that Prolene is polypropylene-based pelvic mesh, just
15 like Marlex is.

16 Q. But, Doctor, have you ever told doctors at UT
17 that using Prolene mesh should not be done in treating
18 SUI or POP?

19 A. Not yet.

20 Q. Doctor, you testified in the Boston Scientific
21 litigation that you couldn't cite any literature that
22 states there's a clinical effect of degradation on a
23 patient. Do you remember that?

24 A. Yes, I do.

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1 Q. And, Doctor, to this day, are you still unaware
2 of any literature that states there's a clinical effect
3 of degradation on the patient?

4 A. No. I've gone and reviewed literature.

5 Q. And, Doctor, are you aware of any literature
6 that states there's a clinical effect of degradation on
7 the patient?

8 A. Yes.

9 Q. And what literature is that?

10 A. The book by Williams is the key reference.

11 Q. What's the name of the book?

12 A. Let me find it. It's in my reference list
13 here.

14 Yeah, it's Reference 44, Essential Biomaterials
15 Science.

16 Q. And that's the key reference that you rely on?

17 A. Yes.

18 Q. Doctor, does the Williams book say anything at
19 all about the clinical effect of degradation of Prolene?

20 A. I don't recall it calling out Prolene by name,
21 but it basically lays out that implants have to be
22 mechanically compatible with the tissue that they're
23 implanted in, and initially a polypropylene mesh,
24 including the Ethicon meshes, are supple and they move

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1 with this soft vaginal tissue, but as the oxidative
2 process takes place, the mesh stiffens, and then it can
3 no longer move with that material.

4 So you've got soft flesh moving and the mesh
5 isn't moving, so there's an abrasion, and this is a sort
6 of thing that can lead to the abrasions that are seen
7 with this mesh.

8 Q. Doctor, stick with me. Are you aware of any
9 literature that states there's a clinical effect of
10 Prolene degradation on a patient? That's my question.

11 A. I may have -- I may very well have seen that in
12 all of my literature review, but I can't call it out as
13 I sit here right at this moment.

14 Q. And you didn't cite any reference in your
15 report that says there's a clinical effect of Prolene
16 degradation on a patient; correct?

17 A. Actually, on thinking about it, I think this
18 Klinge article, Reference 42, calls this out.

19 Q. And what does it say about the clinical effect
20 of Prolene degradation on a patient?

21 MR. MONSOUR: I'm going to object to form. Can
22 I ask you one question just for clarity's sake? Are
23 you talking about polypropylene articles, or are you
24 talking --

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1 actually increasing the molecular weight because you're
2 incorporating oxygen into it.

3 Q. Doctor, there must be a loss of molecular
4 weight for degradation to occur; correct?

5 A. Must be a loss of? Well, with polymers, if
6 you're talking about oxidative degradation of
7 polypropylene, you will see a reduction in molecular
8 weight.

9 Q. Thank you. And there must be -- there must be
10 a reduction in molecular weight for degradation for a
11 polymer; correct? You can't have one without the other?

12 A. Degradation? Yes, you can. You can have
13 chemical changes. Remember, I defined degradation as
14 chemical changes in the polymer. You could have
15 oxidation occurring at some level not to the point where
16 it actually starts to cleave the chain and you will see
17 increase in the molecular weight of the material.

18 Q. But, Doctor, for oxidative degradation to
19 occur, there must be loss of molecular weight; correct?

20 A. Yes, when oxidative degradation of
21 polypropylene occurs, there is degradation of molecular
22 weight.

23 Q. And when oxidative degradation of Prolene
24 occurs, there must be loss of molecular weight; correct?

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1 **A.** There will be reduction in molecular weight.

2 And I want to be specific about molecular weight.

3 Molecular weight is a term that gets tossed around
4 loosely a lot with polymers, but there are different
5 types of average molecular weights.

6 **Q.** Right.

7 **A.** Number average, weight average.

8 **Q.** I'm going to get to those in just a minute.

9 But if oxidation occurs, you must have cleavage of the
10 polymer chain?

11 **A.** Oxidative degradation of polypropylene does
12 lead to chain cleavage, that's correct.

13 **Q.** And oxidative degradation of Prolene leads to
14 strong carbonyl bands present on FTIR that weren't there
15 before; correct?

16 **A.** Correct.

17 **Q.** And strong -- I'm sorry.

18 Oxidative degradation of Prolene leads to
19 reduced physical properties; correct?

20 **A.** It changes physical properties. It depends on
21 the particular one whether it's reduced or not.

22 **Q.** And when the polymer chain is cleaved, there's
23 a reduction in physical properties; correct?

24 **A.** Well, you have to specify which one.

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1 Prolene.

2 Q. Right. But, Doctor, I'm asking you for solid
3 scientific data. Other than Costello, are you aware of
4 any solid scientific data that shows Prolene has
5 diminished physical properties?

6 A. There's also data in Ethicon's own studies
7 where in one instance material retained only 54 percent
8 of its initial strength after oxidative degradation.

9 Q. Doctor, you're talking about the 1983 document
10 from Ethicon?

11 A. I'd have to look at it. There's a couple of
12 1983 documents, but that sounds about right.

13 Q. But when we're talking about the suture
14 retained only 54 percent of its original strength,
15 you'll agree that in that study only one explanted fiber
16 was tested?

17 A. I'd have to look at that study to say.

18 Q. Okay. Do you have that study with you?

19 A. I believe I do.

20 What was the number on that one? I'd have to
21 go back to my report and track it down that way.

22 Q. ETH.MESH.15955438?

23 A. Okay.

24 Q. Are you there with me, Doctor?

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1 **A.** I am in that document, yes.

2 **Q.** And, Doctor, you'll agree that only one
3 explanted fiber was tested, would you not?

4 **A.** It was 5-0 Prolene from Specimen 2.

5 **Q.** But one explanted fiber was tested; correct?

6 **A.** They performed tests on one explanted fiber,
7 but there's no indication of how many times that might
8 have been tested.

9 **Q.** And, Doctor, as a scientist, would you ever
10 rely on one data point in drawing conclusions for a
11 paper that you'd present to the American Chemical
12 Society?

13 **A.** Well, my point is, they may have actually
14 tested that sample multiple times.

15 **Q.** But my question to you, Doctor, and listen
16 closely to my question: Would you ever rely, as a
17 scientist, on one data point in drawing a conclusion for
18 a paper that you'd present to the American Chemical
19 Society?

20 **A.** I would rely on one data point, but I would
21 want more data, and what they show in this paper is
22 there's evidence of other fibers cracking.

23 **Q.** And, Doctor, did you rule out that the fiber
24 had been damaged by a scalpel? Did you rule that out?

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1 **A.** You would think that they would not test
2 material that had been damaged by a scalpel.

3 **Q.** How did you rule that out?

4 **A.** I don't have the fiber to examine.

5 **Q.** And you didn't rule that out that the fiber had
6 been damaged by a scalpel, had you?

7 **A.** Well, I trust that Ethicon hires good
8 scientists who would be careful.

9 **Q.** Did you rule out the fact that Ethicon's fiber
10 was damaged by a scalpel?

11 **A.** I have no evidence that it was.

12 **Q.** If you look at -- going back to your report, on
13 page 5, where we discussed chain scission, chain
14 scission produces carbonyl bands; correct?

15 **A.** Chain scission in polypropylene accompanies the
16 formation of carbonyl bands. It's not that chain
17 scission produces it, but --

18 **Q.** And chain scission in Prolene accompanies the
19 formulation of carbonyl bands; correct?

20 **A.** Yes.

21 **Q.** In fact, Doctor, a carbonyl band from oxidation
22 is one of the most intensely absorbing functional groups
23 on FTIR; correct?

24 **A.** Yes, it's one that's easy to see.

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1 **A.** For oxidized Prolene, I think that's the one.

2 **Q.** Costello is the one you're relying on?

3 **A.** Yeah. There's actually two Costello papers,
4 yeah.

5 **Q.** Doctor, have you ever seen carbonyl bands from
6 Prolene after it was implanted in vivo?

7 **A.** Well, as we just said, I've seen evidence
8 gathered by Ethicon scientists and also from Costello.

9 **Q.** But outside of the documents that you've
10 reviewed, the internal documents and peer-reviewed
11 literature, Doctor, have you ever seen an FTIR spectra
12 that has a carbonyl band at or around 1750 for oxidized
13 Prolene?

14 **A.** You mean with my -- something we generated in
15 the lab?

16 **Q.** Yes, sir.

17 **A.** No.

18 **Q.** With your own eyes.

19 **A.** No, we have not.

20 **Q.** And, Doctor, have you ever done an FTIR spectra
21 for Prolene?

22 **A.** For polypropylene, yes. For Prolene, no.

23 **Q.** Doctor, you had the equipment at your lab at UT
24 to do an FTIR spectra on Prolene, didn't you?

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1 **A.** Yes.

2 **Q.** In fact, that was something easy for you to do;
3 correct?

4 **A.** It is easy, yes.

5 **Q.** In fact, that's something you could have done;
6 correct?

7 **A.** Yes.

8 **Q.** Are you an expert in FTIR?

9 **A.** I would say I'm quite experienced with it. We
10 use it routinely to characterize polymers that we've
11 made.

12 **Q.** But do you hold yourself as an expert in FTIR?

13 **A.** Well, I'm not a person who's specialized in
14 spectroscopy my whole career, but we use it as a tool
15 routinely.

16 **Q.** Doctor, do you tell the students you teach at
17 UT that you're an expert in FTIR analysis?

18 **A.** I wouldn't classify myself as an expert.
19 There's certainly people that practice it day in and day
20 out that know more about it than I do.

21 **Q.** And, Doctor, do you know -- well, by the way,
22 FTIR is a way to confirm oxidation?

23 **A.** Yes.

24 **Q.** And do you know where on an FTIR spectra a

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1 Q. Okay. Let's look at -- continuing on page 15,
2 at the bottom, you cite the Mary article?

3 A. Yes.

4 Q. And we've talked about Mary already; is that
5 right?

6 A. Yes.

7 Q. And, Doctor, you'll agree that the authors in
8 Mary did not recognize 1740 as a wavelength for DLTDP?

9 A. I don't know that, but I have no evidence that
10 they explicitly pointed that out.

11 Q. Well, did the study -- did the Mary study, sir,
12 recognize a 1740 wavelength for DLTDP?

13 A. I did not see that called out in there.

14 Q. And, in fact, sir, if -- how would you know
15 that -- first of all, Prolene has DLTDP in it, doesn't
16 it?

17 A. Yes, it does.

18 Q. And if the Mary article did not have a
19 wavelength at 1740 reciprocal centimeters for DLTDP, how
20 in the world do you know it's Prolene that they were
21 looking at?

22 A. I'm not sure I follow you.

23 Q. Okay. Well, the FTIR analysis in Mary did not
24 show a peak at 1740 reciprocal centimeters?

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1 **A.** Can we look in there?

2 **Q.** Absolutely.

3 **A.** They did carry out a cleaning study.

4 **Q.** My question is, sir: The FTIR analysis in Mary
5 did not show a peak at 1740 reciprocal centimeters for
6 the DLTDP wavelength; correct?

7 **A.** They measured the absorbance at 1740.

8 **Q.** Yes, sir, but did they recognize that
9 wavelength for DLTDP, is my question?

10 **A.** They did not, but they had cleaned the sample,
11 and that would remove surface antioxidants. Plus, the
12 sutures had been in the body for two years, which would
13 also deplete antioxidants present at the surface.

14 **Q.** The authors in Mary didn't compare the
15 elongation of Prolene to PVDF, did they?

16 **A.** Compare the elongation of the Prolene and the
17 PVDF?

18 **Q.** That's correct.

19 **A.** PVDF? I don't see the comparison.

20 **Q.** Doctor, on page 20 of your expert report,
21 there's an SEM photograph?

22 **A.** Yes.

23 **Q.** That's not a -- that's not a Prolene product,
24 is it? Top of page 20.

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1 compared to Dog Site 3 and Dog Site 2. Do you see that?
2 Down at the bottom.

3 A. Yes.

4 Q. And what do you notice about the change of
5 molecular weight, Doctor?

6 A. I notice that those are not changing very much.

7 Q. And that was done by GPC; correct?

8 A. Yeah, I would assume so. That's how these
9 values are normally derived.

10 Q. And, in fact, at the bottom, under conclusions,
11 it says: "Comparison of 7-year explants to current
12 Prolene indicate no molecular weight degradation."

13 Did I read that correctly?

14 A. That's what it says.

15 Q. Any reason to dispute that, Doctor?

16 A. Well, I would need to have more details about
17 what they did, because they're also carrying out
18 intrinsic viscosity measurements here, these IV
19 measurements, and it's not clear to me whether they're
20 deriving these MW values from that IV measurement.
21 That's commonly done.

22 And maybe they're getting these number average
23 molecular weights from GPC. I simply don't know. They
24 don't clearly tell me where these values are coming

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1 decision.

2 Q. Do you have any reason to believe that these
3 sutures were plasticized?

4 A. It is possible that polypropylene does undergo
5 some plasticization inside the body.

6 Q. And, Doctor, plasticization would improve
7 toughness, wouldn't it?

8 A. Plasticization would soften the material.

9 Q. But it would improve toughness? I'm asking
10 about toughness. I'm not asking about softening the
11 material. Toughness.

12 A. Plasticization at a reasonable level would
13 probably improve the toughness of the material.

14 Q. Okay. And, Doctor, if toughness of the
15 material improves, then we can rule out degradation,
16 can't we?

17 A. That's not strictly true.

18 Q. But, Doctor, as a general rule, you will agree
19 that as toughness improves, degradation can be ruled
20 out; correct?

21 A. I would not make a general statement about
22 that. I'd have to consider the specific material.

23 Q. Doctor, would that be consistent with the
24 principles of polymerization that you used to teach your

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1 C E R T I F I C A T E

2

3 I, JOAN L. PITT, Registered Merit Reporter,
4 Certified Realtime Reporter, and Florida Professional
5 Reporter, do hereby certify that, pursuant to notice,
6 the deposition of JIMMY W. MAYS, PhD, was duly taken on
7 March 2, 2016, at 8:36, before me.

8 The said JIMMY W. MAYS, PhD, was duly sworn by
9 me according to law to tell the truth, the whole truth,
10 and nothing but the truth, and thereupon did testify as
11 set forth in the above transcript of testimony. The
12 testimony was taken down stenographically by me. I do
13 further certify that the above deposition is full,
14 complete, and a true record of all the testimony given
15 by the said witness.

16

17

18 _____
JOAN L. PITT, RMR, CRR, FPR

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23 supervision of the certifying reporter.)

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